1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DENNLER et al.

Serial No. 09/601,534

Filed: August 28, 2000

Title: METHOD OF SCREENING THERAPEUTIC AGENTS

Atty Dkt. 1430-245
C# M#

Group Art Unit: 1642

Examiner: Tran, M.

Date: March 13, 2001

OIPE MAR 13 2001 PATENT & TRADEMARK OFFICE TC1647

RECEIVED
MAR 15 2001
TECH CENTER 1600/2900

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

Fees are attached as calculated below:

Total effective claims after amendment **0** minus highest number previously paid for **20** (at least 20) = 0 x $ 18.00	$	0.00
Independent claims after amendment **0** minus highest number previously paid for **3** (at least 3) = 0 x $ 80.00	$	0.00
If proper multiple dependent claims now added for first time, add $270.00 (ignore improper)	$	0.00
Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) ($110.00/1 month; $390.00/2 months; $890.00/3 months)	$	0.00
Terminal disclaimer enclosed, add $ 110.00	$	0.00
☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) ($710.00) ☐ Please enter the previously unentered , filed ☐ Submission attached	$	0.00
Subtotal	$	**0.00**
If "small entity," then enter half (1/2) of subtotal and subtract ☐ Statement filed herewith	-$	0.00
Rule 56 Information Disclosure Statement Filing Fee ($180.00)	$	0.00
Assignment Recording Fee ($40.00)	$	0.00
Other:		**0.00**
TOTAL FEE ENCLOSED	$	**0.00**

The Commissioner is hereby authorized to charge any deficiency in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

1100 North Glebe Road, 8th Floor
Arlington, Virginia 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100
MJW:tat

NIXON & VANDERHYE P.C.
By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

DENNLER et al. Atty. Ref.: 1430-245

Serial No.: 09/601,234 Group Art Unit: 1642

Filed: August 28, 2000 Examiner: Tran, M.

For: METHOD OF SCREENING THERAPEUTIC AGENTS

* * * * *

March 13, 2001

RESPONSE

Hon. Commissioner of Patents
and Trademarks
Washington, DC 20231

Sir:

In response to the Examiner's requirement for restriction, set forth in the Office Action dated February 13, 2001, Applicants elect the subject matter of Group I (claims 1-6) for prosecution in this application. The election is made with traverse.

The requirement for restriction appears to be based on the Examiner's perception that the subject matter of claim 1 has no special technical feature that defines a contribution to the art beyond that previously disclosed by Yingling et al. Applicants respectfully disagree.

The Examiner contends that Yingling et al discloses the effects of Smad protein on TGF-β gene regulation.

Applicants submit that the Examiner has construed the teaching of the citation too broadly.

Yingling et al have shown that Smad3 and Smad4 form a complex that recognizes a bipartite binding site within the AP-1 sites of the artificial TGF-β responsive p3Tp-Lux vector. The citation provides no explicit teaching as to which recognition sequence on the AP-1 sites is involved in binding. Only with the benefit of hindsight (i.e., with an appreciation of Applicants' disclosure) is it possible to implicitly deduce that a related recognition sequence, 5' AGTCAGACA 3' may be responsible for Smad binding on the artificial construct. It is submitted that the skilled person reading the citation at the time of publication would not have appreciated the inherent role of the "CAGA box" in the TGF-β intracelular signalling pathway.

The crux of the present invention lies in the identification of the recognition sequence 5' WXYCAGACZ 3' and the discovery that Smad3/Smad4 binding thereto is an essential component of TGF-β induced gene transcription. Yingling et al have observed that "the Smad binding site (in AP-1) is not required for transcriptional activity in response to TGF-β or Smad3/Smad4 cooverexpression." It is submitted that these findings constitute a prejudicial

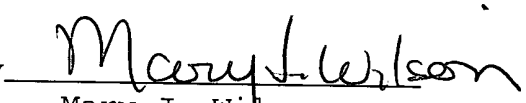
"teaching away" from the ambit of the presently claimed invention.

Based upon these differences it is submitted that the present invention provides a clear technical feature that extends beyond the teaching of the art. All of the claims incorporate the novel recognition sequence 5' WXYCAGACZ 3' and thus can be considered to have a common unifying feature. Withdrawal of the requirement for restriction is clearly in order and same is requested.

An early and favorable Action on the merits is awaited.

Respectfully submitted,

NIXON & VANDERHYE, P.C.

By 
Mary J. Wilson
Reg. No. 32,955

MJW:tat

1100 North Glebe Road
8th Floor
Arlington, Virginia 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100